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10/580,613

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Leif Hermansson

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WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/580,613 | Applicant(s) HERMANSSON ET AL. | |
| | Examiner BETHANY BARHAM | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 21-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/30/06, 4/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of IDS's filed on 10/30/06 and 4/23/07 is acknowledged. Receipt of Applicant's response filed on 10/15/09 is also acknowledged. Claims 1-35 are pending.

Election/Restrictions

Applicant's election of claims 1-20 in the reply filed on 10/15/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL. Claims 1-20 are rejected.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claim 6 and 13, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cini et al (as cited in Applicant's IDS).

The instant claims are directed to a coated implant for in vivo-anchoring to a biological tissue or another implant, which coated implant comprises an implant having a pre-treated surface and on said pre-treated surface one or more layers of mainly non-hydrated chemically bonded ceramic material, characterized in that each layer of said ceramic material independently comprises a first binder phase selected from the group

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consisting of aluminates, silicates, phosphates, sulphates and combinations thereof, and that said ceramic material is chemically and/or mechanically bound to said implant.

- Cini et al teaches ceramic pellet implants of calcium aluminate and that the implants are hydrated after contact with tissue fluid (pg. 441 summary) (meeting the limitations of instant claims 1-4 and 14).
- $12\text{CaO}7\text{Al}_2\text{O}_3$ and CaOAl_2O_3 are taught by Cini et al and have an apparent porosity of 45.8% (pg. 442, 2nd paragraph) (meeting the limitations of instant claims 5).

Claims 1-7, 9, 13-15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,655,777 ('777) as evidenced by Cini et al.

- '777 teaches a biodegradable prostheses or implant comprising fibers of ceramic powders such as CaAl on alternating layers of film (calcium aluminate) (abstract, claim 8). '777 teaches various layers of the fibers on a polymer sheet with no fibers of various thicknesses (col. 11, lines 9-22) (meeting the limitations of instant claims 1-4 and 9).
- Various CaAl are taught including CaOAl_2O_3 (col. 4, lines 13-22). $12\text{CaO}7\text{Al}_2\text{O}_3$ and CaOAl_2O_3 are taught by Cini et al and have an apparent porosity of 45.8% (pg. 442, 2nd paragraph) (meeting the limitations of instant claims 5 and 7).
- Phosphate fibers are also taught by '777 (abstract, col. 2, lines 55-57) meeting the limitations of instant claims 6).

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- According to '777 the implant is made of polymers such as PLGA and is used as bone plates or orthopedic devices (abstract, col. 2, lines 46-52) (meeting the limitations of instant claims 13-15).
- '777 teaches particle sizes 1-2 microns (col. 4, lines 55) (meeting the limitations of claims 18-20).

Claims 1-5, 7, 9, and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,237,559 ('559).

- '559 teaches a composite ceramic bone implant comprising a first ceramic member such as alumina or calcium aluminate with a porosity of 20% and a second ceramic member disposed on the first such as calcium aluminate preferably with a porosity of 40% (abstract, Fig and claims 1-2; col. 2, lines 10-39) (meeting the limitations of claims 1-5, 7 and 9).
- '559 teaches a ceramic bone implant of alumina that is oxidized (claims 1, col. 3, lines 49-55, col. 8, lines 39-67) (meeting the limitations of claims 13-17).
- '559 teaches a particle size of 1-20 microns (col. 4, lines 4-5) (meeting the limitations of claims 18-20).

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0247903 ('903) as evidenced by Cini et al.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under

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35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

- '903 teaches coatings for medical implants comprising calcium aluminate (CA) alone and that the surface is pretreated [0030,0036,0044-0048, 0080-0083] (meeting the limitations of instant claims 1-4).
- '903 teaches various CA stoichiometries, CA or CA₂ or C₁₂A₇, etc [0059] and Ra values of 0.1-10 microns, specifically 0.5-0.7 [0045, 0081]. According to Cini et al CA and C₁₂A₇ have porosities of 45.8% (pg. 442, 2nd paragraph) (meeting the limitations of instant claims 5, 7-9 and 11).
- '903 teaches including phosphates or salts thereof in the coatings [0075] (meeting the limitations of instant claims 6).
- '903 teaches thicknesses of 1.0-200 microns, preferably less than 30 microns, and Examples of 0-22 micron thickness and 8 micron particle sizes are taught [0069,0048,0082-0083] (meeting the limitations of claims 10, 12 and 18-20).
- '903 teaches various implants such as medical implants, bone implants, orthopedic implants, etc which are made of ceramic, metallic or polymeric material such as titanium, etc [0034-0035] (meeting the limitations of claims 13-15).
- '903 teaches that the surface is oxidized with aluminate [0081] (meeting the limitations of claims 16-17).

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Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0215484 ('484).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

- '484 teaches a ceramic coating on a substrate that is preparing by pretreating the substrate and applying at least one layer of non-hydrated powder mixture on the substrate and application of second layers is also taught (abstract, claim 1, [0023-0024]) (meeting the limitations of instant claims 1-4).
- '484 teaches various CA stoichiometries, CA or CA₂ or C₁₂A₇, etc [0059] of 0.5-20 microns [0033-0034] and Ra values of 0.1-10 microns, specifically 0.6-0.7 [0039, 0056]. Porosities of 30-40% are taught [0060] (meeting the limitations of instant claims 5, 7-9 and 11).
- '484 teaches including phosphates or salts thereof in the coatings [0052] (meeting the limitations of instant claims 6).
- '484 teaches thicknesses of 20-50 microns, and Examples of 22 micron thickness or less than 10 micron particle sizes are taught [0056-0059] (meeting the limitations of claims 10, 12 and 18-20).

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- '484 teaches various implants such as medical implants, bone implants, orthopedic implants, etc which are made of ceramic, metallic or polymeric material such as titanium, etc [0044,0056] (meeting the limitations of claims 13-15).
- '484 teaches that the surface is oxidized with aluminate [0056] (meeting the limitations of claims 16-17).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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